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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,175	07/23/2003	Thomas P. Osypka	(49363) 58953	8248

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EXAMINER	
JACKSON, BRYAN M	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,175	OSYPKA, THOMAS P.	
	Examiner	Art Unit	
	Bryan M. Jackson	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2003 and 05 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 2/27/04 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Claims 1-4, 13-14, 16-17, 23-24, 32-33, 36, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1, 23, and 36, a "bipolar cardiac lead" (ln 1) is recited, the examiner inquires whether or not a bipolar cardiac lead contains more than one electrode or "an electrode" as recited.

As to claims 1, 23, and 36, "to affix the electrode housing to the cardiac tissue" is recited, an apparatus cannot claim connection to a human, it is suggested to use "adopted to" or "for affixing".

As to claim 1, it is unclear what "electrically active" means (ln 10), no pulse generator has been set forth to apply a potential, therefore making a screw electrically active.

As to claim 2, "externally threaded plug" and "internally threaded collar" are recited, these terms are inferentially included, it is unclear if applicant is

positively reciting them or functionally reciting them. They should be positively set forth first before they are use in the claim.

As to claim 3, "self-sealing opening" is recited, this term is inferentially included, it is unclear if applicant is positively reciting them or functionally reciting them. They should be positively set forth first before they are use in the claim.

As to claims 4 and 24, a "screwdriver tipped stylet" lacks antecedent basis due to the lack of an active claim language in claims 3 and 23 (i.e. "configured for engagement with a screwdriver"). It is unclear if the Applicant is positively reciting them or functionally reciting them. They should be positively set forth first before they are use in the claim.

As to claims 13-14, 32-33, and 46, "anode" and "cathode" are recited, no voltage generator has been set forth to apply a potential, it is suggested to use "adapted to serve".

As to claims 16 and 17, an apparatus cannot claim connection to a human, it is suggested to use "adapted to penetrate".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, 20, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiss et al. (4299239). Weiss et al. discloses an Epicardial heart lead assembly, a helical-shaped screw (fig 5B, 50), an insertion tool considered to be a guiding sheath (fig 4A, 60), wherein a screwdriver tool (fig 4A, 70) is inserted into the insertion tool, a coil conductor (fig 1, 34), and membrane (fig 1, 52).

Claims 1, 20, 22-23, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachon (5531780). Vachon discloses a pacing lead (fig 1, 20), electrode assembly (fig 1, 36), considered to be an electrode housing, a helical electrode (fig 2, 82), and connector assembly (fig 1, 28).

Claims 1, 20, 22-23, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Helland (5545201). Helland discloses a bipolar pacing lead (fig 2, 20), a helical electrode (fig 3, 44), connector assembly (fig 2, 28), and internal bore (fig 4, 74) capable of functioning as a screwdriver tip.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before

> the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 20, 22-23, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Doan et al. (68199590).

Doan et al. discloses pacing lead (fig 1, 20), helical electrode (fig 2, 44), spiral track member (fig 6, 122) and follower member (fig 6, 140), and connector assembly (fig 1, 28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4, 23-25, 31, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. (4299239) in view of Doan et al. (6819959).

Weiss et al. discloses the claimed invention except for the externally threaded plug and internally threaded collar. Doan et al. teaches that it is known to use spiral track member (fig 6, 122) and follower member (fig 6, 140) to provide a means for screwing a helical-shaped electrode into the heart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al., with a spiral track member and follower member, wherein the follower member is not externally threaded but

capable of performing a corkscrew-like rotation, as taught by Doan et al., in order to provide a means for screwing a helical-shaped electrode into the heart.

Claims 7, 13-14, 38, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. in view of Dutcher el al. (4357946).

Weiss et al. discloses the claimed invention except for the ring electrode and the use of a ring electrode as an anode and a helical screw as a cathode. Dutcher el al. teaches that it is known to use a ring electrode (fig 3, 38) as an anode and a helical fixation screw as a cathode to provide a bipolar pacing mode (col 1 ln 64-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al., with a ring electrode as an anode and a helical fixation screw as a cathode, as taught by Dutcher el al., in order to provide a means for a bipolar pacing mode.

Claims 14-15 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. and Dutcher et al. as applied to claims 7 and 37 above, and further in view of Helland (5545201).

Weiss et al. and Dutcher et al. discloses the claimed invention except for the insulator and proximal portion of a helical screw as an anode. Helland teaches that it is known to use a center electrode (fig 3, 46), an intermediate insulator (fig 3, 48), and an outer electrode (fig 3, 50) to provide a proximal portion of a helical screw electrode as an anode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify

the devices of Weiss et al. and Dutcher et al., with a center electrode, an intermediate insulator, and an outer electrode, as taught by Helland, in order to provide a helical screw electrode the capability to function as an anode and cathode.

Claims 8-10, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. and Dutcher el al. as applied to claim 7 above, and further in view of Gates (5697964).

Weiss et al. and Dutcher et al. disclose the claimed invention except for the insulating tube including silicone and a steroid. Gates teaches that it is known to use steroid-silicone compound ring (fig 2, 40) considered to be an insulating tube to provide the elution of a steroid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al. and the ring electrode of Dutcher et al., with the steroid-silicone compound ring, as taught by Gates, in order to provide insulation between a helical screw and ring electrode, and the elution of a steroid to eliminate inflammation in a biological organism.

Claims 12, 18, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al., Dutcher et al., and Gates as applied to claim 10 above, and further in view of Vachon (5531780).

Weiss et al., Dutcher et al., and Gates discloses the claimed invention except for the about 15% to 25% by weight of steroid. Vachon teaches that it is

known to use between 0.01% to 50% by weight steroid (col 8, ln 25-26) in a steroid-eluting dart structure (fig 2, 62) to provide an anti-inflammatory or therapeutic reaction within a biological organism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices of Weiss et al., Dutcher et al., and Gates, with a steroid-eluting dart structure with between 0.01% to 50% by weight steroid, wherein 15% to 25% by weight steroid is within the range of 0.01% to 50% by weight steroid, as taught by Vachon, in order to provide an anti-inflammatory or therapeutic reaction within a biological organism.

Weiss et al. discloses the claimed invention except for the fixation pin within a helical screw. Vachon teaches that it is known to use a pointed projection (fig 6, 172) considered to be a pin to provide fixation to heart tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al., with a pointed projection within a helical screw electrode, as taught by Vachon, in order to provide fixation to heart tissue.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. in view of Rubin (5374287).

Weiss et al. discloses the claimed invention except for the helical screw penetrating heart tissue up to about 10mm or in the range of 3mm to 10mm. Rubin teaches that it is known to use corkscrew-shaped electrodes having a length of about 5 mm to provide pacing and sensing of cardiac signals. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al., with corkscrew-shaped electrodes having a length of about 5 mm, wherein 5mm is considered to be about 10mm and within the range of 3mm to 10mm, as taught by Rubin, in order to provide penetration into the heart tissue of up to 5mm to pace and sense cardiac signals.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. in view of Rubin (5374287) and Vachon (5531780).

Weiss et al. discloses the claimed invention but does not disclose expressly the length of 7mm to 10mm for a helical screw and a length of 5mm to 7mm for a fixation pin. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the corkscrew-shaped electrodes having a length of about 5 mm, as taught by Rubin, and a pointed projection considered to be a fixation pin, as taught by Vachon, with the length of 7mm to 10mm for a helical screw and a length of 5mm to 7mm for a fixation pin, because Applicant has not disclosed that the length of 7mm to 10mm for a helical screw and a length of 5mm to 7mm for a fixation pin provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with corkscrew-shaped electrodes having a length of about 5 mm, as taught by Rubin, and a pointed projection considered to be a fixation pin, as taught by Vachon, because it provides penetration into heart tissue to pace and sense cardiac signals, and fixation to the heart tissue, and since it appears to be an

arbitrary design consideration which fails to patentably distinguish over Rubin and Vachon.

Therefore, it would have been an obvious matter of design choice to modify Rubin and Vachon to obtain the invention as specified in the claim(s).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss in view of Gates (5697964).

Weiss et al. discloses the claimed invention except for the insulating sheath of biocompatible material. Gates teaches that it is known to use a cylindrical element (fig 4, 110) covering a conductor coil, which is preferably formed from a biocompatible nonconductive material (col 6, ln 11-13) to eliminate rejection of a foreign object within a biological organism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al., with a cylindrical element covering a conductor coil, which is preferably formed from a biocompatible nonconductive material, as taught by Gates, in order to eliminate rejection of a foreign object within a biological organism.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss in view of Vachon (5531780).

Weiss et al. discloses the claimed invention except for the connector. Vachon teaches that it is known to use a connector assembly (fig 1, 28) at a proximal end of a pacing lead to provide an electrical connection from a power

source to the heart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al., with a connector assembly at a proximal end of a pacing lead as taught by Vachon, in order to provide an electrical connection from a power source to the heart.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss and Doan as applied to claim 23 above, and further in view of Gates (5697964) and Dutcher et al. (4357946).

Weiss et al. and Doan et al. disclose the claimed invention except for the insulating tube including silicone and a steroid. Gates teaches that it is known to use steroid-silicone compound ring (fig 2, 40) considered to be an insulating tube to provide the elution of a steroid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices of Weiss et al. and Doan et al., with the ring electrode of as taught by Dutcher et al., and with the steroid-silicone compound ring, as taught by Gates, in order to provide the elution of a steroid via an insulating tube-shaped structure within an electrode ring.

Weiss et al. and Doan et al. disclose the claimed invention except for the ring electrode and the use of a ring electrode as an anode and a helical screw as a cathode. Dutcher el al. teaches that it is known to use a ring electrode (fig 3, 38) as an anode and a helical fixation screw as a cathode to provide a bipolar pacing mode (col 1, ln 64-66). It would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the devices of Weiss et al. and Doan et al., with a ring electrode as an anode and a helical fixation screw as a cathode, as taught by Dutcher el al., in order to provide a means for a bipolar pacing mode.

As to claims 11, 29, and 42, Weiss et al., Dutcher et al., Doan et al., and Gates disclose the claimed invention except for durometer of about 40 to 90 Shore A. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a durometer of about 40 to 90 Shore A, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al., Doan et al., Dutcher et al., and Gates as applied to claim 28 above, and further in view of Vachon (5531780).

Weiss et al., Dutcher et al., Doan et al., and Gates disclose the claimed invention except for the about 15% to 25% by weight of steroid. Vachon teaches that it is known to use between 0.01% to 50% by weight steroid (col 8, ln 25-26) in a steroid-eluting dart structure (fig 2, 62) to provide an anti-inflammatory or therapeutic reaction within a biological organism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices of Weiss et al., Dutcher et al., Doan et al., and Gates, with a steroid-

eluting dart structure with between 0.01% to 50% by weight steroid, wherein 15% to 25% by weight steroid is within the range of 0.01% to 50% by weight steroid, as taught by Vachon, in order to provide an anti-inflammatory or therapeutic reaction within a biological organism.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. and Doan et al. as applied to claim 31 above, and further in view of Dutcher et al. (4357946).

Weiss et al. and Doan et al. disclose the claimed invention except for the ring electrode and the use of a ring electrode as an anode and a helical screw as a cathode. Dutcher el al. teaches that it is known to use a ring electrode (fig 3, 38) as an anode and a helical fixation screw as a cathode to provide a bipolar pacing mode (col 1, ln 64-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiss et al. and Doan et al., with a ring electrode as an anode and a helical fixation screw as a cathode, as taught by Dutcher el al., in order to provide a means for a bipolar pacing mode.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al., Doan et al., and Dutcher as applied to claim 33 above, and further in view of Helland (5545201).

Weiss et al., Doan et al., and Dutcher et al. disclose the claimed invention except for the insulator and proximal portion of a helical screw as an anode.

Helland teaches that it is known to use a center electrode (fig 3, 46), an intermediate insulator (fig 3, 48), and an outer electrode (fig 3, 50) to provide a proximal portion of a helical screw electrode as an anode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices of Weiss et al., Doan et al., and Dutcher et al., with a center electrode, an intermediate insulator, and an outer electrode, as taught by Helland, in order to provide a helical screw electrode the capability to function as an anode and cathode.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berthelsen (4953564) discloses a screw-in drug eluting lead.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/28/6